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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,826	02/08/2002	Mitchell F. Brin	17326CIP2 (BOT)	2841

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/071,826	BRIN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 34-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 34-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 28, 2008 has been entered.

2. Claims 11 and 34-44 are pending.

Claims 11 and 35 have been amended.

Claims 11 and 34-44 are examined on the merits.

Withdrawn Objection

Claim Objections

3. Claim 35 is no longer objected to because it no longer depends from cancelled claim 12.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The rejection of claims 11 and 35-40 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a mammary

gland disorder, which is an atypical tissue with botulinum toxin type A, does not reasonably provide enablement for preventing the development of an atypical tissue, thereby treating a mammary gland is withdrawn in light of Applicants' amendment to claim 11.

Claim Rejections - 35 USC § 103

5. The rejection of claims 11, 34-38, 40-42 and 44 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2001/0043930 A1 (effective filing date December 28, 1993), and further in view of Wald and Kakulas (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964) is withdrawn.

6. The rejection of claims 11 and 34-44 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2001/0043930 A1 (effective filing date December 28, 1993), and further in view of Wald and Kakulas (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964) and U.S. Patent number 6,312,708 (filed July 21, 2000) is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 11 and 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2001/0043930 A1 (effective filing date December 28, 1993), and further in view of Wald and Kakulas (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964) and U.S. Patent number 6,312,708 (filed July 21, 2000) as evidenced by Vakil et al. (C. M. A Journal 109: 29-32, July 7, 1973).

In anticipation of the former pending 103 rejections Applicants' argue the Office has misconstrued the teachings of Wald and have supplied a definition of mucus, see pages 8 and 9. Applicants are steadfast in their assertion "...the teachings of Wald and Klaus as a whole and in their proper context", as well as the basis for the combination of references does not exist, see page 9, 2nd paragraph. Applicants conclude arguments contending "[t]he combination of documents is ...hindsight reconstruction", See page 9, 2nd paragraph. These points of view and Applicants" arguments have been carefully considered, but found unpersuasive.

Foremost, Vakil notes mammary and certain axillary sweat glands are histologically of the apocrine type and their secretions are biochemically similar. It is clear from Wald two facts, the gland elaborated upon in the article is the breast and a substance is emitted from the gland. While Applicants note Wald on page 203, left column, 4th-6th paragraphs, establish apocrine glands elaborate a definite substance which Applicants note is an odiferous secretion it is nonetheless a secretion and

Applicants' claims do not limit in any particular type of secretion. Nevertheless, the glands of the breast are known in the art to emit secretions as evidenced by Vakil.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, publication '3930 provides the motivation to treat any conditions, which include excessive mucus secretions with botulinum toxin A, see page 1, section 0014; and page 2, section 0017. As set forth in the instant rejection it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was treat a mammary gland disorder

with botulinum toxin type A in order to cause regression and/or remission of the atypical breast tissue.

The publication teaches the local administration of botulinum toxin type A to a patient suffering from a disease or conditions such as excessive sweating, lacrimation and mucus secretions, see abstract; page 1, section 0014; page 2, section 0017; and page 4, Example 5. The publication does not teach treating a mammary gland disorder with administration of the recited dosages in claims 11, 34, 37, 39 and 43 to the mammary gland and the implantation of a botulinum toxin implant.

However, Wald and Kakulas teach aprocrine gland carcinoma of the breast, which releases a substance, see page 203, column 1, last paragraph. The patent teaches a biodegradable polymer implant capable of releasing botulinum toxin A for various disease conditions, see column 16, lines 53-60. The patent also teaches the amount of botulinum A to be injected is generally between about 0.01 units per kilogram to about 35 units per kg, see bridging paragraphs of columns 25 and 26. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of all of the documents because the publication teaches treating various disorders with botulinum toxins and suggests modifications can be made, see page 5, section 0069.

One of ordinary skill in the art would have been motivated to treat apocrine gland carcinoma of the breast with botulinum toxin A using the designated dosages with a reasonable expectation of success by teachings well known in the art, because of the successful treatment of secretions and it is art known that dosages of any composition

for treatment must be adjusted and optimized, see publication, page 2, sections 0026 and 0027; and page 4, section 0061. Moreover, one of ordinary skill in the art would have motivated to do so with a reasonable expectation of success by teachings in all the references, that medical devices, such as implants are well known in the art for providing controlled or sustained release of pharmaceutical agents to treat disease.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 11 and 34-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/929,040 (filed August 27, 2004). Although the conflicting claims are not identical, they are not patentably distinct from each other because both

set of claims read on treating a cancer or neoplastic disease, whereby botulinum toxin type A is administered. While claims 1-13 of the copending application '040 read broadly treating a cancer including a plethora of neoplasms, these claims include treating a mammary gland cancer the active steps are the same as the instant application's, administering a botulinum toxin to tissues or cells. Both sets of claims encompass the treatment of breast cancer with botulinum toxin, in particular botulinum toxin type A.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 11 and 34-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-28 and 31 of copending Application No. 11/192,777 (filed December 11, 2007). Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope. Both sets of claims read on treating a mammary gland disorder whereby botulinum toxin is administered.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
27 May 2008

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643